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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,029	09/28/2001	Lurie Keith	016354-004500US	4197

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EXAMINER

PATEL, MITAL B

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/967,029

Applicant(s)

LURIE ET AL.

Examiner

Mital B. Patel

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment/Arguments

1. This Office Action is in response to the Amendment filed 12/10/02.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 12/10/02 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 7, 8, 9, 10, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Biondi et al (US 5377671).
5. **As to claim 1**, Biondi teaches a method for administering a drug to a patient, the method comprising coupling a valve system to the patient's airway (**Col. 3, lines 10-24**), wherein the valve system is configured to prevent or impede respiratory gases from flowing into the lungs for at least some time such that the intrathoracic pressure is less

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than atmospheric pressure (**Col. 4, lines 36-46**); introducing a drug into the patient; lowering the intrathoracic pressure using the valve system to cause blood to flow into the thorax and thereby increasing vital organ perfusion to enhance circulation of the drug (**Col. 2, lines 26-34**).

6. **As to claim 3**, Biondi teaches a method wherein the intrathoracic pressure is reduced by breathing in while preventing or inhibiting respiratory gas flow to the lungs with the valve system.
7. **As to claim 7**, Biondi teaches a method wherein the drug is administered by a process selected from a group consisting of intravenously, through the patient's bone, through the patient's airway, orally, nasally, endobronchially, rectally, and transdermally.
8. **As to claim 8**, Biondi teaches a method wherein the drug is administered through a facial mask or the valve system.
9. **As to claim 9**, Biondi teaches a method wherein the drugs are selected from a group consisting of glucose, sodium bicarbonate, oxygen, steroids, vasopressor drugs, anti-arrhythmic drugs, anti-seizure, anti-asthma, anesthetics, and cooling solutions to cool the brain during cardiac arrest.
10. **As to claim 10**, Biondi teaches a method wherein the valve system is configured to permit respiratory gases to exit the patient's lungs, and further comprising forcing respiratory gases from the lungs and out the valve system.
11. **As to claim 13**, Biondi teaches a method wherein the valve system is coupled to an inhalation device (in this case a ventilator and tracheal tube, **see Col. 3, lines 10-15**)

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that includes the drug (oxygen), and further comprising inhaling from the inhalation device to administer the drug.

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Federowicz et al (US 5927273).

13. **As to claim 1**, Federowicz teaches a method for administering a drug to a patient, the method comprising coupling a valve system **46** to the patient's airway, wherein the valve system is configured to prevent or impede respiratory gases from flowing into the lungs for at least some time such that the intrathoracic pressure is less than atmospheric pressure (**Col. 10, lines 45-49**); introducing a drug into the patient; lowering the intrathoracic pressure using the valve system to cause blood to flow into the thorax and thereby increasing vital organ perfusion to enhance circulation of the drug (**Col. 10, lines 36-53**).

14. **As to claim 2**, Federowicz teaches a method wherein the patient is under cardiac arrest, and wherein the intrathoracic pressure is reduced during a decompression phase of CPR when performing CPR and also preventing or inhibiting respiratory gas flow into the lungs with the valve system (**Col. 10, lines 36-53**).

15. Claims 1, 4, 5, 6, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Lurie et al (US 6463327).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the

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reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

16. **As to claim 1**, Lurie teaches a method for administering a drug to a patient, the method comprising coupling a valve system to the patient's airway (**Col. 16, lines 56-66**), wherein the valve system is configured to prevent or impede respiratory gases from flowing into the lungs for at least some time such that the intrathoracic pressure is less than atmospheric pressure (**Col. 16, lines 56-66**); introducing a drug into the patient; lowering the intrathoracic pressure using the valve system to cause blood to flow into the thorax and thereby increasing vital organ perfusion to enhance circulation of the drug (**Col. 2, lines 55-65**).

17. **As to claim 4**, Lurie teaches a method wherein the intrathoracic pressure is reduced by stimulating the phrenic nerve to cause the respiratory or abdominal muscles to contract while preventing or inhibiting respiratory gas flow to the lungs with the valve system (**Col. 5, lines 58-62**).

18. **As to claim 5**, Lurie teaches a method wherein the intrathoracic pressure is reduced by squeezing the chest and relaxing the chest with a chest caress **10,12** while preventing or inhibiting airflow to the lungs with the valve system

19. **As to claim 6**, Lurie teaches a method wherein the valve system is configured to prevent respiratory gases from entering the lungs until a magnitude of a threshold negative intrathoracic pressure in the range from 0 cm H₂O to about 40 cm H₂O is exceeded (**Col. 31, lines 56-59**).

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20. **As to claim 11**, Lurie teaches a method wherein the valve system is configured to prevent respiratory gases from exiting the patient's lungs until a positive end expiratory pressure in the range from about 0 cm H₂O to about 20 cm H₂O is exceeded (Col. 25, lines 8-9).

21. **As to claim 12**, Lurie teaches a method wherein the valve system is coupled to a facial mask 352 that is placed over the mouth and nose, and further comprising removing the drug from the drug storage compartment of the facial mask.

Conclusion

1. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6374827, US 5743864, US 5150291, US 4928674, US 4928674, and US 4326507.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp
February 22, 2003



WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700